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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,710	03/30/2000	Anders Dahlqvist	3377/99-Util	9098

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/537,710

Applicant(s)

DAHLQVIST ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-32,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-32,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 01 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>5/9/07</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2007 has been entered.

2. Applicant's response to the Final Office Action mailed November 22, 2006 on April 23, 2007 is acknowledged.

3. Claims 30-32 and 36-37 are pending and are under examination.

Specification Objection

4. The specification is objected to because of the following informalities:

The specification is objected to because the word "variants" is misspelled as "variantes", see page 5, line 22 of the specification.

The specification is objected to because the sequence notation is improper, see page 11 where the following appears "SEQ. ID. NO." (and throughout the specification).

Claim Objection

5. Claims 30-32 are objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 30 is amended to recite,

"A process for the production of triacylglycerol, comprising:

growing a transgenic cell containing:

(i) the nucleotide sequence of SEQ ID NO:1 from *Saccharomyces cerevisiae*, or

(ii) the nucleotide sequence that is 95% identical to SEQ ID NO:1, wherein the nucleotide sequence of (i) and (ii) encode an enzyme (SEQ ID NO:2) that catalyzes in an acyl-CoA-independent reaction the transfer of fatty acids from phospholipids to diacylglycerol in the biosynthetic pathway for the production of triacylglycerol".

Claim 31 is objected to for the recitation of "S. cerevisiae" instead of "*Saccharomyces cerevisiae*". For clarity it is suggested that claim 31 is amended to recite,

"A method of producing triacylglycerol and/or triacylglycerols with uncommon fatty acids comprising:

transforming an organism or host cell with:

(i) the nucleotide sequence of SEQ ID NO:1 from *Saccharomyces cerevisiae*, or

(ii) the nucleotide sequence that is 95% identical to SEQ ID NO:1, wherein the nucleotide sequence of (i) and (ii) encodes SEQ ID NO:2, whereby the transformation results in the production of) that catalyzes in an acyl-CoA-independent reaction the transfer of fatty acids from phospholipids to diacylglycerol in the biosynthetic pathway for the production of triacylglycerol and/or triacylglycerols ". See also claim 32.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30-32 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of using a transgenic cell or transgenic organism to produce triacylglycerol. On page 8 of the specification, it is disclosed that the transgenic cell or organism is preferably a plant cell, yeast cell or plant. However the claims broadly recite "a transgenic cell or organism" which reads on any type of cell or organism. The specification also discloses on page 8, that the transgenic cell or organism is a eukaryote. Page 10 of the specification discloses the transformation of transgenic oil accumulating organisms. Moreover, on page 12, it is disclosed that the transgenic organisms are plants, fungi and animals. Further, in the instant specification, an enzyme activity is described as phospholipid: diacylglycerol transferase (PDAT). Some plants, and not others, have this activity (see page 16 of the instant specification). A yeast gene, YNR008w, was tested for this activity and was confirmed to be a PDAT that can be over expressed in yeast and *A. thaliana* to increase fatty acid content in cells.

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The specification also describes numerous shorter DNA's and encoded proteins putatively described as PDAT genes; however, no testing on these gene fragments has been preformed to confirm the proposed function. Thus, one species of the claimed genus has been fully described, that is the use of the *S. cerevisiae* sequence (SEQ ID NOs:1 and 2) to produce transgenic organism (plant and yeast) with increased triacylglycerol production. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Further, no relationship between the disclosed species and the structures of the other proposed species is described. No common characteristics, other than the enzyme function, is required in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus based on the instant disclosure, because there is no showing of a transgenic organism that is an animal as disclosed. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

7. Claims 30-32 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of making triacylglycerol using a yeast or plant organism transformed with a gene encoding PDAT from *S. cerevisiae* (SEQ ID NO:1), does not reasonably provide enablement for methods of making triacylglycerol comprising growing any transgenic cell or organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

Undue experimentation would be required to grow any known organism transgenically containing transformed with a gene encoding PDAT. In the instant specification, an enzyme activity is described as phospholipids: diacylglycerol transferase (PDAT). Some plants, and not others, have this activity (see page 16 of the instant specification). A yeast gene, YNR008w, was tested for this activity and was confirmed to be a PDAT that can be over expressed in yeast and

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A. thaliana to increase fatty acid content in cells. The specification also describes numerous shorter DNA's and encoded proteins putatively described as PDAT genes; however, no testing on these gene fragments has been performed to confirm this function.

The instant specification proposes 5 additional species of PDAT genes (6 total) and provides guidance and working examples to test for their activity. However, the nature of the invention is that genes encoding PDAT must be known to practice the claimed invention; the prior art provides none of these with respect to structure and related function. Further, the claims broadly read on any animal/organism, whereas the instant specification only exemplifies a yeast and plant.

Additionally, the claims are not enabled for methods to produce triacylglycerol with uncommon fatty acids in organisms without the ability to natively produce triacylglycerol with uncommon fatty acids. To make some cells that produce TAG with uncommon fatty acids would require undue experimentation absent adequate guidance. Page 1 of the instant specification describes the claimed invention as being able to produce uncommon fatty acids "in combination with a gene for the synthesis of an uncommon fatty acid"; the PDAT gene does not regulate this process. Thus, to effectively practice the claimed methods, one would be required to use organisms that naturally produce uncommon fatty acids or to use organisms also transformed with a gene for the synthesis of an uncommon fatty acid. The specification provides no guidance or working examples for producing uncommon fatty acids in the absence of uncommon fatty acid genes (either endogenous or exogenous).

Moreover, the claims are directed to a method to produce host cells with increased overall oil content and the instant specification is not enabled for said method. The specification

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describes methods that increase the fatty acid content of host cells wherein a PDAT gene is over-expressed (see page 19, and Table 2), however, the specification does not describe increasing the overall oil content of the host organism, especially any known organism, which is a distinct method. As noted in WO 96/38573 on page 1, "[c]urrently, there are no documented demonstrations of increase in oil content by transgenic means...[i]n contrast, increased in the proportions of some strategic fatty acids have been achieved by the introduction of various plant fatty acid biosynthesis and acyltransferase genes in oilseeds". The state of the art provides no examples to support the scope of the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art. Further, attempting to find additional PDAT genes and use them in the claimed methods or to make some cells that produce TAG with uncommon fatty acids or a construct a method to produce host cells with increased overall oil content or a method which utilizes any transgenic organism, would constitute undue experimentation absent adequate guidance in the specification. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and

distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 30-32 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 30 is indefinite for the recitation of "the nucleotide sequence encoding an enzyme is expressed" because there is no nexus between the nucleotide that encodes SEQ ID NO:2 and the recited enzyme. Is SEQ ID NO:2 the structure of the enzyme? Thus, the claim lacks clear antecedent basis for "the nucleotide sequence encoding an enzyme is expressed" because it is unclear which of (i) or (ii) encodes the recited enzyme since the claim recites that they encode SEQ ID NO:2.

Claim 31 is indefinite because the method does appear to have met the objective of the method. Note that the preamble of the claim recites "producing triacylglycerol and or triacylglycerols", however, the end point of the method is "an increased oil content of the cell or organism?

Claim 32 is indefinite because the method is open ended. Note that the method does not recite an end point or demonstrate that the preamble was achieved.

Claim 36 is indefinite for the recitation of "the method of claim 31 wherein the nucleotide encoding an enzyme is expressed", because it is unclear which of (i) or (ii) is being referred to and if SEQ ID NO:2 is the structure of the enzyme. The lacks clear antecedent basis for " the nucleotide sequence encoding an enzyme" as claim 31 does not set forth that an enzyme is encoded. See also claim 37 for the same reason.

Response to Applicant's Arguments:

9. Applicant's arguments have been fully considered. Note that the rejections of record are withdrawn and new rejections/objections have been instituted for the reasons stated above.

Conclusion

10. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

HR
6/14/07

HOPE ROBINSON
PRIMARY EXAMINER